

EXPLANATORY STATEMENT

National Health Act 1953

National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020.

The Pharmaceutical Benefits Scheme (PBS) is established under the *National Health Act 1953* (the Act) and provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The Act regulates the listing, prescribing, pricing, charging and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits.

Section 100 of the Act provides that the Minister may make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to persons:

- a) Who are living in isolated areas: or
- b) Who are receiving treatment in circumstance which pharmaceutical benefits are inadequate for that treatment; or
- c) If the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

As part of the COVID-19 National Health Plan temporary Medicare Benefits Schedule (MBS) items allow doctors, nurses, midwives and mental health professionals to deliver services via telehealth, provided those services are bulk billed. These arrangements are described at *Health Insurance (Section 3C General Medical Services –COVID-19 Services) Determination 2020*.

In support of the Telehealth measure the Australian Government is fast tracking the implementation of Electronic Prescribing to help protect people most at-risk in the community from exposure to COVID-19. Under this measure, Electronic Prescribing is being fast tracked to 80 percent of general practices and community pharmacies over the next eight weeks with expected commencement by May 2020. The rapid spread of COVID-19 has made it clear that the community, including health professionals are in need of an interim solution to ensure people who are confined to their home can access necessary medicines prior to the implementation of Fast Track Electronic Prescribing.

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* (the Special Arrangement) has been developed under Section 100 of the Act to provide an interim measure to provide a patient who is confined to home access to necessary medicine through “Image Based Prescription for Medicine Supply”.

The Special Arrangement allows prescribers and patients to provide a pharmacy with a digital image of their prescription via fax, email or text message, enabling the pharmacy to dispense their medicines, and deliver or post them to the patient. The patient or prescriber would then be required to supply the pharmacy with the paper prescription within 15 days.

The Special Arrangement is restricted to those patients who are vulnerable and have had a telehealth consultation as described at the *Health Insurance (Section 3C General Medical Services –COVID-19 Services) Determination 2020*. The exception to this is a patient who is self-isolating and has an existing prescription issued prior to self-isolation and not part of the

telehealth measure – e.g. repeat. In this circumstance the patient may create an image of the prescription and forward it to the pharmacy of their choice to gain supply.

The Special Arrangement applies to all pharmaceutical benefits available for supply under Part VII of the Act other than Schedule 8 and 4(D) medicines such as opioids and Fentanyl. These are high-risk medicines that pose significant risks to the community including misuse and diversion. If an urgent supply of these medicines is required, this can be provided under existing provisions in section 48 of the National Health (Pharmaceutical Benefits) Regulations 2017.

Community pharmacy have also raised concerns surrounding the PBS requirement for patients (or a nominated agent) to sign the prescription to acknowledge receipt of supply of a pharmaceutical benefit due to potential contamination risks of people in the pharmacy using pens to sign for this purpose in the current COVID-19 environment.

The Special Arrangement temporarily allows the supply of a pharmaceutical benefit without acknowledgement from the patient wherever it is impractical for them to sign the prescription (e.g. where the patient is concerned about transmission of COVID-19 by using the pharmacy pen) until the cessation of the Medical Benefits Scheme (MBS) Telehealth measure under the COVID-19 National Health Plan. Pharmacists are still expected to ask patients to acknowledge receipt of the pharmaceutical benefit where practical, however pharmacists are not required to sign on the patient's behalf where it is not practical do so (e.g. the pharmacist supplying medicine from an image based prescription). This measure should be used as an exception, not a rule, and pharmacists are required to use their professional judgement in these circumstances and implement localised processes for vulnerable patients.

The Special Arrangement will be repealed on 30 September 2020 in line with the Telehealth measure. There is provision to extend the Special Arrangement instrument if the telehealth measure is extended past 30 September 2020.

The Department has consulted with clinical peak bodies and industry regarding the requirement for an interim measure prior to the implementation of Fast Track Electronic Prescribing. The Department has informed the Department of Veteran Affairs, the Department of Human Services and state and territory governments through the Electronic Prescribing Working Group (EPWG) about the Special Arrangement.

The Act specifies no conditions that need to be satisfied before the power to make the Special Arrangement is exercised.

The Special Arrangement is a legislative instrument for the purposes of the *Legislation Act 2003*.

The Special Arrangement commenced on 26 March 2020.

Authority: section 100 under the *National Health Act 1953*

Details of the National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020

Part 1 – Preliminary

Section 1 – Name

This section provides that the title of the instrument is the *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020*

Section 2 – Commencement

This section provides that the instrument commences on 26 March 2020.

Section 3 – Authority

This section provides that the instrument is made under section 100 of the *National Health Act 1953*(the Act).

Section 4 – Repeal of this instrument

This section provides that the instrument is repealed at the start of 30 September 2020.

Section 5 – Simplified Outline of this instrument

This section provides a simplified outline of the Special Arrangement to make the supply of pharmaceutical benefits to patients at risk of COVID-19.

Section 6 – Definitions

This section provides definitions for terms used in the Special Arrangement.

Part 2 – Division 1- Preliminary

Section 7 – Pharmaceutical benefits provided for under this Special Arrangement

This item describes which pharmaceutical benefits are available under the Special Arrangement

Subsection (1) refers to Division 2 of the Special Arrangement - *Requirements for supply of pharmaceutical benefit - paper-based prescriptions* and states that all pharmaceutical benefits available for supply under Part VII of the Act with the exclusion of Schedule 8 and Schedule 4(D) are available to be supplied under the Special Arrangement.

Subsection (2) refers to Division 3 of the Special Arrangement - *Requirements for receipt of a pharmaceutical benefit-all prescriptions* and states the Special Arrangement applies to all pharmaceutical benefits available for supply under Part VII of the Act.

Section 8 – Application of Part VII of the National Health Act

This item specifies that this Special Arrangement applies to Part VII of the Act (Pharmaceutical Benefits) or regulations or other instruments made for Part VII of the Act.

Section 9 – Supplies to which the Special Arrangement applies

This item describes the supply to which the Special Arrangement applies.

Subsection (1)

- (a) refers to Division 2 of the Special Arrangement - *Requirements for supply of pharmaceutical benefit - paper-based prescriptions* and states that the Special Arrangement applies to the supply of a pharmaceutical benefit based on a paper-based prescription (excluding medication chart prescription) to a patient at risk of COVID -19 (whether or not for the person's own use) or
- (b) (i) and (ii) allows for a patient to have the supply of a pharmaceutical benefit from a paper based prescription written as a result of a telehealth or phone attendance prior to the commencement of this Special Arrangement but after the provision for the new telehealth arrangements.

Subsection (2) refers to Division 3 of the Special Arrangement- *Requirements for receipt of a pharmaceutical benefit-all prescriptions* and states that this Special Arrangement applies to the supply of a pharmaceutical benefit made by an approved pharmacist or approved medical prescriber, meaning the provision for the patient or the pharmacist to acknowledge the receipt of the pharmaceutical benefit has been removed.

Division 2 – Requirements for supply of pharmaceutical benefit - paper-based prescriptions

Section 10 – Modified application of section 44 of the Regulations to supplies of pharmaceutical benefits based on supplies to which Division 2 of Special Arrangement applies.

This item provides for the modified application of section 44 of the Regulations to allow supply of a pharmaceutical benefit based on the provisions in this Special Arrangement.

Subsection (1) states that section 44 of the Regulation are modified to provide for the supply of a pharmaceutical benefit based on the provision in this Special Arrangement.

Subsection (2) states that an approved pharmacist or an approved medical practitioner may supply the pharmaceutical benefit to person on the first presentation of a prescription if:

- under Subsection (2) (a) an approved pharmacist or an approved medical practitioner provides supply of a pharmaceutical benefit under section 44 of the Regulations upon the receipt of a digital image of the prescription or an image of the details of the prescription as described in subsections 40(1), (2) and (2A) of the Regulations; or
- under Subsection (2)(b) that a PBS prescribers advises the approved pharmacist or approved medical practitioner the details of the prescription; or
- under Subsection (2)(c) , a PBS prescriber have given the approved pharmacist or approved medical practitioner a copy of the prescription.

Subsection (3) states that if the prescription is or would be an authority prescription, the supplier may supply the pharmaceutical benefit under subsection (1) only if:

- Under Subsection (3)(a)(i)(ii) the pharmaceutical benefit prescribed has a relevant streamlined authority code and the PBS prescriber informs the supplier of that code or the digital image displays that code, or
- Under Subsection (3)(b)(i)(ii) the minister or Chief Executive Medicare has notified the PBS prescriber that each authorisation will be given and the PBS prescriber informs the supplier that notification prior to the pharmaceutical benefit being supplied.

Subsection (4) states that a PBS Prescriber as referred to in Section 2 ensures that the pharmacist/patient copy and the Medicare/DVA copy of the prescription is received by the

relevant pharmacist or medical practitioner no later than 15 days after the day the pharmaceutical benefit was supplied.

Subsection (5) states that a PBS Prescriber who provided an approved pharmacist or approved medical practitioner with details of the prescription under subsection (2)(b) ensures that the pharmacist/patient copy and the Medicare/DVA copy of the prescription is received by the relevant pharmacist or medical practitioner no later than 15 days after the day the pharmaceutical benefit was supplied.

Subsection (6) (a)(i)(ii) states that this section does not apply to a pharmaceutical benefit if the pharmaceutical benefit would be supplied by an approved pharmacist and the prescription must be written under a State or Territory law where the premises, at or from where the pharmaceutical benefit would be supplied is located.

Subsection (6) (b)(i)(ii) states that this section does not apply to a pharmaceutical benefit if the pharmaceutical benefit would be supplied by an approved medical practitioner and the prescription must be in writing under a law in force in the area where the medical practitioner is approved.

Section 11 – Notations and endorsements to prescriptions

This item relates to any notations and endorsements made to the prescription by an approved pharmacist or approved medical practitioner, and ensures that these notations and endorsements are noted on the legal paper prescriptions when it is received by the approved supplier or as soon as practicable.

Division 3 – Requirements for receipt of a pharmaceutical benefit- all prescriptions

Section 12 – Application of Section 57 of the Regulations to supplies of pharmaceutical benefits based on prescriptions to which Division 3 of Special Arrangement applies.

This item refers to the application of section 57 of the regulations in respect to the acknowledgment of receipt of the pharmaceutical benefit.

Subsection (1) states that section 57 of the regulations does not apply to the supply of a pharmaceutical benefit where it is not practicable for the approved supplier to obtain from the person receiving the pharmaceutical benefit written acknowledgement of the receipt of the pharmaceutical benefit.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*

National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* makes a special arrangement to make the supply of pharmaceutical benefits to patients at risk of the COVID-19, or who have been prescribed a pharmaceutical benefit by a health professional at risk of COVID-19 virus, more convenient and effective.

The instrument modifies arrangements for the supply of a pharmaceutical benefit on a paper prescription before the presentation of that prescription to the approved pharmacist or approved medical practitioner making the supply.

This instrument also removes the need for a person in receipt of a pharmaceutical benefit to acknowledge the receipt of the pharmaceutical benefit upon supply.

Human rights implications

Broadly, the PBS is a benefits scheme which assists with providing subsidised access to medicines for people in the community. It engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), as it is a positive step towards attaining the highest standard of health for all Australians, and it assists in the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* is compatible with Articles 2 and 12 of the ICESCR as they contribute to the efficient operation and effective administration of the scheme.

The Section 100 Special Arrangement is made under the *National Health Act*.

Conclusion

The *National Health (COVID-19 Supply of Pharmaceutical Benefits) Special Arrangement 2020* are compatible with human rights as they do not raise any human rights issues or impinge on any applicable rights or freedoms.

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